REMARKS

This Amendment is in response to the Office Action mailed April 22, 2002, wherein the Examiner:

(1) acknowledged Applicants' response to the Office Action mailed July 5, 2001 and entered it into the record;

(2) withdrew objections to no specific reference for prior applications and an improper information disclosure statement;

(3) maintained objections to the declaration and drawings;

(4) withdrew rejections of claims 1-8 under 35 U.S.C. § 102(b) and 103(a);

(5) objected to claims 1-8 for informal matters;

(6) rejected claims 1-8 under 35 U.S.C. § 112, second paragraph;

(7) rejected claims 1, 2, 5 and 6 under 35 U.S.C. § 102(b) as being anticipated by Greilberger et al. (Arteriosclerosis, Thrombosis and Vascular Biology, Vol. 17, No. 11, pages 2721-2728, November 1997) ("Greilberger"); and

(8) rejected claims 3-4 and 7-8 under 35 U.S.C. § 103(a) as being unpatentable over Greilberger in view of Kaiserling et al. (Gastroenterology, 1996, Vol. 110, pages 369-374) ("Kaiserling");

INTRODUCTION

By the present amendment, Applicants have amended claims 1-8 to place this application in condition for allowance. No new matter has been added. Consequently, claims 1-8 currently remain pending.

Entry of this Amendment and early reconsideration of this application are respectfully requested.

1. ACKNOWLEDGEMENT

Applicants wish to thank the Examiner for entering the previous response filed by Applicants on November 5, 2001 into the record and providing such a thorough and complete final Office Action.

2. OBJECTION WITHDRAWAL

Applicants wish to thank the examiner for withdrawing her objections to the reference to prior applications in response to Applicants' amendment of the specification. Applicants further wish to thank the Examiner for withdrawing her objection to an improper information disclosure statement as Applicants were not attempting to create such a statement.

3. OBJECTIONS MAINTAINED

In response to the Examiner's continued objection to the declaration, Applicants respectfully submit that the new declaration was inadvertently not included with the previous response as indicated therein. The new declaration is now submitted herewith.

In response to the Examiner's continued objection to the drawings, Applicants submit formal drawings herewith which overcome the Examiner's and Draftsperson's objections thereto.

4. REJECTIONS WITHDRAWN

Applicants wish to thank the Examiner for the careful and thoughtful examination of the previously amended claims 1-8 and the remarks which

addressed the Examiner's prior rejections. As the previous amended claims 1-8 defined over the prior art originally cited by the Examiner, so also do the currently amended claims 1-8 define over the most recent prior art cited by the Examiner.

5. OBJECTED CLAIMS

The Examiner objected to misspellings in claim 1, line 5; claim 2 and claim 6. Applicants respectfully submit that claims 1-8, as amended, overcome these objections. Accordingly, Applicants respectfully request that the Examiner withdraw these objections.

6. CLAIMS REJECTED UNDER § 112

The Examiner rejected claims 1-8 under 35 U.S.C. § 112, second paragraph, as being indefinite. The Applicants respectfully submit that claims 1-8, as now amended, overcome this rejection. Namely, claim 1 has been amended to address the positive limitation for the recitation of "arteriosclerosis diagnosis." Markush group expressions have been properly formatted. Claim 1 has been amended to recite a method "comprising ...." Moreover, claim 1 has been amended to recite all essential steps in the claimed method. Accordingly, Applicants respectfully request that the Examiner withdraw this rejection.

7. CLAIMS REJECTED UNDER § 102(b)

The Examiner has finally rejected claims 1, 2, 5 and 6 under 35 U.S.C. § 102(b) as being anticipated by Greilberger, which is newly cited prior art.

(A) Finality Premature

Applicants respectfully submit that the final Office Action in this application is premature under MPEP §706.07(a). The Examiner has made a final rejection on prior art not of record in response to amended claims which include all the limitations of the originally filed claims which the Examiner should reasonably expect to be claimed. The amended claim 1 submitted November 5, 2001 was only amended to overcome §112 indefiniteness problems. The words added to claim 1 were "an immunological detecting method." The Examiner should have reasonably expected such an addition to claim 1 as the specification clearly discloses and refers to the use of various immunological detecting methods in connection with the measuring subject. No new matter was added. The remainder of the language in amended claim 1 is unchanged from the originally filed claim, aside from §112 corrections. Therefore, entry of a final rejection is premature.

Accordingly, Applicants respectfully request that the Examiner withdraw the finality of the rejection in accordance with MPEP §706.07(d).

(B) Lack of Anticipation

The standard for lack of anticipation is one of strict identity. To anticipate a claim for a patent, a single prior source must contain **all** its essential elements. Apple Computer, Inc. v. Articulate Systems, Inc., 234 F.3d 14, 20 57 USPQ2d 1057, 1061 (Fed. Cir. 2000) (emphasis added). Moreover, a printed publication must adequately describe the invention to a person with ordinary skill in the art to which the invention pertains. The

description must enable such a person not only to comprehend the invention, but also to make it.

Greilberger describes and teaches a method of extracting LDL from human blood, artificially oxidizing the LDL and forming a complex of the artificially oxidized LDL and another substance. In other words, the LDL must be artificially oxidized external to the human body in order to form the complexes so described.

Greilberger in fact, teaches away from the present invention, because Greilberger's investigation is based on the basic understanding that oxidized LDL does not exist in blood drawn from a human vein or artery, and not an affected part. This fundamental misunderstanding clearly illustrates that Greilberger does not describe **all** the essential elements of the invention. Furthermore, Greilberger does not disclose, describe, teach or suggest the diagnosing step as required in claim 1 as amended.

All prior art references cited by the Examiner in this application fails to disclose, teach or describe that oxidized LDL is present in the human body outside an arteriosclerotic lesion. This is because the accepted and conventional understanding of the prior art before the present invention was that plenty of anti-oxidant substances exist in "blood" and experimentally prepared oxidized LDL, given to "blood," is quickly taken in by the liver and eliminated from the "blood."

Accordingly, Greilberger fails to disclose each step of claim 1 of the present invention and, therefore, cannot anticipate, nor make obvious. Claim 1, as amended, is submitted to be in condition for allowance.

Claims 2, 5, and 6 each depend directly or indirectly from claim 1. Therefore, claims 2, 5 and 6 are each allowable for the reasons stated above with respect to claim 1.

8. CLAIMS REJECTED UNDER §103(a)

The Examiner has rejected claims 3-4 and 7-8 under 35 U.S.C. §103(a) as unpatentable over Greilberger in view of Kaiserling.

Claims 3-4 and 7-8 each depend directly or indirectly from claim 1. Greilberger does not anticipate claim 1, as amended, for the reasons discussed above. Thus, claims 3-4 and 7-8 are also allowable for the reasons discussed above, with respect to claim 1.

CONCLUSION

For the reasons set forth above it is respectfully requested that the rejection of the claims be withdrawn and the pending claims allowed. A favorable response is earnestly solicited.

Respectfully submitted,

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Dated: June 24, 2002

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ATTACHMENT B

MARKED UP VERSION OF CLAIMS

1. A method for ~~detecting oxidized LDL for~~ arteriosclerosis diagnosis ~~characterized in that~~ **comprising the steps:**

drawing blood from a human vein or artery, not an affected part;

measuring quantitatively, by an immunological detecting method ~~is used in which,~~ a ~~measuring subject is~~**concentration of** a complex **present** in **the drawn** blood ~~taken from a human body of oxidized lower density liloprotein (~~**comprising** oxidized LDL~~)~~ and one substance ~~selected~~ from **the group consisting of** an acute phase reactant, blood coagulation-~~-~~fibrinolytic related protein and a disinfectant substance produced by macrophages~~.~~**;**

and

~~2. The method for detecting oxidized LDL for~~

diagnosing the onset of arteriosclerosis ~~diagnosis according to Claim 1, characterized in that:~~**based on the measured concentration of the complex.**

2. ~~an~~**The method as recited in claim 1, wherein the** acute phase reactant is selected from **the group consisting of** α1-antitrypsin, fibrinogen, fibronectin, lipoprotein (a), C-reactive protein (CRP), Serum

amyloid A (SAA), Serum amyloid P component (SAP), α2-macroglobulin, α1-antichymotrypsin, α1-acidoglycoprotein and a complement component.

~~3. The method for detecting oxidized LDL for arteriosclerosis diagnosis according to Claim 1, characterized in that:~~

3. The method as recited in claim 1, wherein the blood coagulation-fibrinolytic related protein is selected from **the group consisting of** a tissue factor, plasminogen, prothrombin, thrombin, antithrombin 3 and a plasmin activator inhibitor 1.

~~4. The method for detecting oxidized LDL for arteriosclerosis diagnosis according to Claim 1, characterized in that:~~

4. ~~a~~**The method as recited in claim 1, wherein the** disinfectant substance produced by macrophages is selected from **the group consisting of** myeloperoxidase, lactoferrin, lysozyme and basic protein.

~~5. The method for detecting oxidized LDL for arteriosclerosis diagnosis according to Claim 1, characterized in that:~~

5. ~~an~~**The method as recited in claim 1, wherein the** immunological detecting method is selected from **the group consisting of** an enzyme immunoassay, a latex flocculation method, an immunological emission spectrochemical analysis and an immunochromato method.

~~6. The method for detecting oxidized LDL for arteriosclerosis diagnosis according to Claim 2, characterized in that:~~

6. ~~said~~**The method as recited in claim 2, wherein the** immunological detecting method is selected from an enzyme immunoassay, a latex flocculation method, an immunological emission spectrochemical analysis and an immunochromato method.

~~7. The method for detecting oxidized LDL for arteriosclerosis diagnosis according to Claim 3, characterized in that:~~

7. ~~said~~**The method as recited in claim 3, wherein the** immunological detecting method is selected from an enzyme immunoassay, a latex flocculation method, an immunological emission spectrochemical analysis and an immunochromato method.

~~8. The method for detecting oxidized LDL for arteriosclerosis diagnosis according to Claim 4, characterized in that:~~

8. ~~said~~**The method as recited in claim 4, wherein the** immunological detecting method is selected from an enzyme immunoassay, a latex flocculation method, an immunological emission spectrochemical analysis and an immunochromato method.